

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Early and locally advanced breast cancer: diagnosis and management

Topic

This guideline will update the NICE guideline on early and locally advanced breast cancer (CG80) as set out in the [surveillance review decision](#).

The guideline will be developed using the methods and processes outlined in [Developing NICE guidelines: the manual](#).

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the [context](#) section.

Who the guideline is for

- Healthcare professionals involved in the multidisciplinary care of people with early and locally advanced breast cancer.
- NHS managers involved in providing multidisciplinary care for people with early and locally advanced breast cancer.
- People using breast cancer services, their family members and carers, and the public.
- Commissioners of breast cancer services (including Clinical Commissioning Groups and NHS England Specialised Commissioning).

It may also be relevant for:

- Healthcare professionals in primary care.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

No equality issues have been identified.

1 What the guideline is about

1.1 Who is the focus?

Groups that will be covered

- Adults (18 and over) with newly diagnosed invasive adenocarcinoma of the breast of any size (T1–T4), with or without spread to locoregional lymph nodes (N0–N3) and with no distant metastases (M0).
- Adults (18 and over) with newly diagnosed ductal carcinoma in situ (DCIS).
- Adults (18 and over) with Paget’s disease of the breast.

Groups that will not be covered

- Adults (18 and over) with invasive adenocarcinoma of the breast and distant metastases (clinical or pathological M1)
- Adults (18 and over) with rare breast tumours (for example, angiosarcoma, lymphoma).
- Adults (18 and over) with benign breast tumours (for example, fibroadenoma).
- Adults (18 and over) with phylloides tumour.
- Adults (18 and over) with locally recurrent breast cancer or DCIS.
- Adults (18 and over) with lobular carcinoma in situ (LCIS).
- Adults (18 and over) with no personal history of breast cancer and an increased risk of breast cancer due to family history.

1.2 Settings

Settings that will be covered

- All settings in which NHS-commissioned care is provided.

1.3 Activities, services or aspects of care

We will look at evidence on the areas listed below when developing the guideline, but it may not be possible to make recommendations on all the areas.

Key areas that will be covered

- 1 Surgery to the breast.
- 2 Management of the positive axilla.
- 3 Adjuvant systemic therapy planning.
- 4 Endocrine therapy for invasive disease.
- 5 Adjuvant chemotherapy.
- 6 Adjuvant biological therapy.
- 7 Adjuvant bisphosphonates.
- 8 Breast radiotherapy.
- 9 Post-mastectomy radiotherapy.
- 10 Neoadjuvant treatment of early and locally advanced breast cancer.
- 11 Lifestyle.

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Areas that will not be covered

- 1 Identifying people in primary care with suspected early and locally advanced breast cancer and referring them to secondary care.
- 2 Bisphosphonates used for the prevention or treatment of osteoporosis.

- 3 The management of breast cancer and related risks in people with a family history of breast cancer.

Areas in the published guideline that will not be updated

- 1 Referral, diagnosis, preoperative assessment and psychological support, including the provision of information.
- 2 Breast reconstruction techniques.
- 3 Complications of local treatment and menopausal symptoms.
- 4 Follow-up

Recommendations in areas that are not being updated may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

1.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective, as appropriate.

1.5 Key issues and questions

While writing this scope, we have identified the following key issues, and draft review questions related to them:

- 1 Surgery to the breast.
 - 1.1 What is the optimal tumour-free tissue margin in people with invasive breast cancer and/or ductal carcinoma in situ (DCIS) treated with breast conserving surgery or mastectomy?
- 2 Management of the positive axilla.
 - 2.1 What are the indications for axillary node clearance when the axilla has been found by biopsy to contain metastatic disease?

- 2.2 What are the indications for nodal radiotherapy after a positive axillary node biopsy (including indications for radiotherapy to internal mammary nodes)?
- 2.3 What are the best strategies for reducing the risk of lymphoedema following axillary surgery?
- 3 Adjuvant systemic therapy planning.
 - 3.1 What is the role of progesterone receptor (PR) testing for adjuvant systemic therapy planning?
 - 3.2 What prognostic tools should be used for determining adjuvant systemic therapy?
- 4 Endocrine therapy for invasive disease.
 - 4.1 What is the optimal adjuvant endocrine therapy for people with oestrogen-positive breast cancer?
 - 4.2 What is the role of ovarian suppression (in addition to standard endocrine therapy) in pre-menopausal women with oestrogen-positive breast cancer?
- 5 Adjuvant chemotherapy.
 - 5.1 What are the optimal adjuvant chemotherapy regimens for people with early and locally advanced breast cancer?
 - 5.2 Which people with early and locally advanced breast cancer would benefit from adjuvant platinum-based chemotherapy?
- 6 Adjuvant biological therapy.
 - 6.1 Which people with T1 N0 human epidermal growth receptor 2 (HER2)-positive breast cancers benefit from adjuvant trastuzumab?
- 7 Adjuvant bisphosphonates.
 - 7.1 What are the indications for using adjuvant bisphosphonates in people with early and locally advanced breast cancer?
- 8 Breast radiotherapy.
 - 8.1 What are the optimal radiotherapy techniques for people with early or locally advanced breast cancer?
 - 8.2 Is there a subgroup of people with early breast cancer who do not need breast radiotherapy after breast-conserving surgery?
- 9 Post-mastectomy radiotherapy.

- 9.1 What are the indications for radiotherapy to the chest wall following mastectomy for people with early and locally advanced breast cancer?
- 9.2 Should the decision on breast reconstruction be deferred until the need for radiotherapy is determined?
- 10 Neoadjuvant treatment of early and locally advanced breast cancer.
 - 10.1 What are the indications for neoadjuvant chemotherapy with or without biological therapy in early and locally advanced breast cancer?
 - 10.2 What are the indications for neoadjuvant endocrine therapy for people with early and locally advanced breast cancer?
 - 10.3 What is the optimal surgical treatment and/or radiotherapy regimen following neoadjuvant systemic therapy?
 - 10.4 What is the role of chemoprevention in women following initial treatment for ductal carcinoma in situ (DCIS)?
- 11 Lifestyle.
 - 11.1 What lifestyle changes improve cancer-specific outcomes in people treated for early and locally advanced breast cancer?

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

1.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

- 1 Overall survival.
- 2 Disease-free survival.
- 3 Disease-related morbidity.
- 4 Treatment-related morbidity.
- 5 Treatment-related mortality.
- 6 Health-related quality of life.
- 7 Patient-reported outcome measures.

2 Links with other NICE guidance, NICE quality standards and NICE Pathways

2.1 NICE guidance

NICE guidance that will be updated by this guideline

- [Breast cancer \(early and locally advanced\)](#) (2009) NICE guideline CG80
- [Trastuzumab for the adjuvant treatment of early-stage HER2-positive breast cancer](#) (2006) NICE technology appraisal guidance 107 (subject to a NICE technology appraisal review consultation)
- [Paclitaxel for the adjuvant treatment of early node-positive breast cancer](#) (2006) NICE technology appraisal guidance 108 (subject to a NICE technology appraisal review consultation)
- [Docetaxel for the adjuvant treatment of early node-positive breast cancer](#) (2006) NICE technology appraisal guidance 109 (subject to a NICE technology appraisal review consultation)
- [Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer](#) (2006) NICE technology appraisal guidance 112

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to early and locally advanced breast cancer:

- [Medicines optimisation](#) (2015) NICE guideline NG5.
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

NICE guidance that is closely related to this guideline

Published

NICE has published the following guidance that is closely related to this guideline:

- [Advanced breast cancer](#) (2009) NICE guideline CG81
- [Improving outcomes in breast cancer](#) (2002) NICE guideline CSG1
- [Improving supportive and palliative care for adults with cancer](#) (2004) NICE guideline CSG4
- [Opioids in palliative care](#) (2012) NICE guideline CG140
- [Neutropenic sepsis](#) (2012) NICE guideline CG151
- [Fertility problems: assessment and treatment](#) (2015) NICE guideline CG156
- [Menopause: diagnosis and management](#) (2015) NICE guideline NG23
- [Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane](#) (2015) NICE technology appraisal guidance 371
- [Familial breast cancer](#) (2013) NICE guideline CG164
- [Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat](#) (2013) NICE diagnostics guidance 10
- [Intraoperative tests \(RD-100i OSNA system and Metasin test\) for detecting sentinel lymph node metastases in breast cancer](#) (2013) NICE diagnostics guidance 8
- [Fulvestrant for the treatment of locally advanced or metastatic breast cancer](#) (2011) NICE technology appraisal guidance 239
- [Eribulin for the treatment of locally advanced or metastatic breast cancer](#) (2012) NICE technology appraisal guidance 250
- [Endoscopic mastectomy and endoscopic wide local excision for breast cancer](#) (2009) NICE interventional procedure guidance 296

- [Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision](#) (2008) NICE interventional procedure guidance 268
- [Interstitial laser therapy for breast cancer](#) (2004) NICE interventional procedure guidance 89
- [Breast reconstruction using lipomodelling after breast cancer treatment](#) (2012) NICE interventional procedure guidance 417
- [Endoscopic axillary lymph node retrieval for breast cancer](#) (2005) NICE interventional procedure guidance 147
- [Laparoscopic mobilisation of the greater omentum for breast reconstruction](#) (2008) NICE interventional procedure guidance 253
- [Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours](#) (2012) NICE technology appraisal guidance 265

In development

NICE is currently developing the following guidance that is closely related to this guideline:

- [Breast cancer \(early\) – intrabeam radiotherapy system](#). NICE technology appraisal. Publication date to be confirmed.
- [Breast cancer \(locally advanced, metastatic\) – eribulin \(after chemotherapy\)](#). NICE technology appraisal. Publication date to be confirmed.
- [Breast cancer \(HER2 positive\) - pertuzumab \(neoadjuvant\)](#). NICE technology appraisal. Publication expected 2016.
- [Breast cancer \(HER2 positive, metastatic\) - pertuzumab \(with trastuzumab and docetaxel\)](#). NICE technology appraisal. Publication date to be confirmed.
- [Breast cancer \(HER2 negative, HR positive\) – everolimus \(with exemestane, after endocrine therapy\)](#). NICE technology appraisal. Publication expected 2017.
- [Breast cancer \(locally advanced or metastatic\) – ixabepilone](#). NICE technology appraisal (suspended).

- [Breast cancer – intensity modulated radiotherapy](#). NICE technology appraisal (discontinued).
- [Breast cancer \(first-line treatment\) – sunitinib \(in combination with a taxane\)](#). NICE technology appraisal (suspended).
- [Bone loss \(therapy-induced\) in non-metastatic breast cancer – denosumab](#). NICE technology appraisal (discontinued).

2.2 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- [Breast cancer](#) (2011) NICE quality standard 12

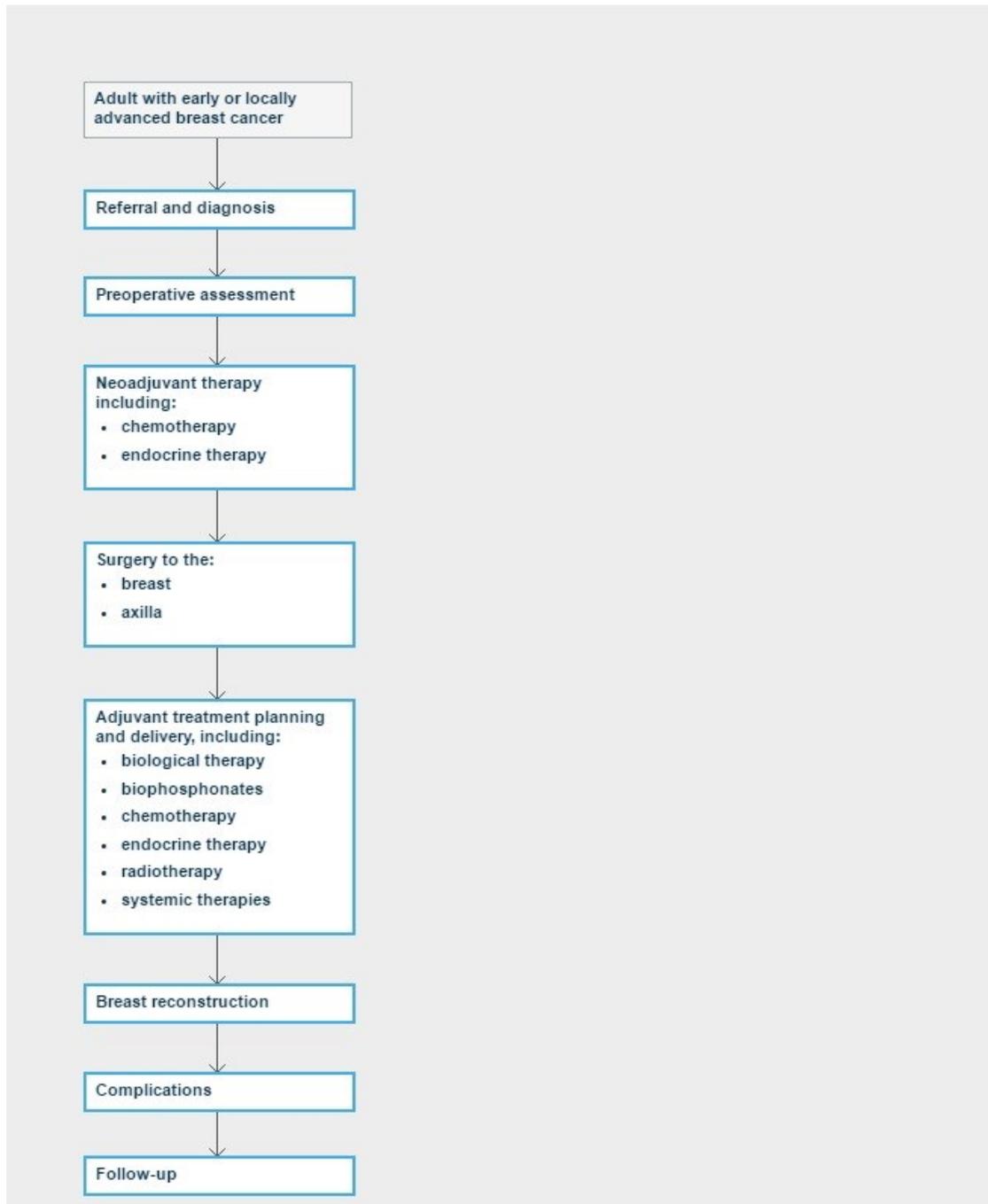
2.3 NICE Pathways

NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

There is a live pathway for [early and locally advanced breast cancer](#).

When the revised guideline is published, the recommendations will be incorporated into a revised pathway. An outline, based on the scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.

Early and locally advanced breast cancer – update outline overview



3 Context

3.1 Key facts and figures

Breast cancer is the most common cancer in the UK with approximately 54,000 new cases of invasive disease and around 7,000 new cases of pre-

invasive (in situ) disease diagnosed annually. The vast majority of breast cancers occur in women, but just over 300 men in the UK are also diagnosed with invasive breast cancer every year.

Most breast cancers are diagnosed at an early stage and are therefore potentially curable with modern treatments. Survival rates have improved over recent decades with almost 90% of women diagnosed with breast cancer surviving their disease for 5 or more years after diagnosis. Survival is however linked to the stage of the disease at diagnosis; only 15% of women diagnosed with stage IV disease are alive at 5 years. Breast cancer remains the leading cause of death in women aged 35–49 years and is second only to lung cancer as the leading cause of cancer death in all women.

The main risk factor for breast cancer is being female; the disease is 100 times less common in men. It is also a disease of aging with risk of breast cancer increasing with increasing age. Some breast cancers are linked to lifestyle factors that include obesity, alcohol intake and use of hormone replacement therapy, whereas other lifestyle factors, including physical activity and breastfeeding, protect against breast cancer. About 5% of breast cancers are due to inherited mutations in high-risk genes such as BRCA1/2 and p53.

3.2 *Current practice*

Breast cancer is diagnosed at specialist breast units across the UK following routine breast screening or GP referral after presentation with suspicious symptoms. At the specialist breast unit, patients are cared for within the context of a specialised multidisciplinary team. Most people are diagnosed with early stage disease and are treated with curative intent. The treatment depends on the type of breast cancer but would generally involve surgery with the addition of drug therapy (including chemotherapy, endocrine therapy and HER2-directed therapy with drugs such as trastuzumab) and radiotherapy, as appropriate.

Some patients present with, or are subsequently diagnosed with, secondary breast cancer. The aim of treatment for these patients is to control the cancer, relieve symptoms and maintain quality of life; all for as long as possible.

Again, different types of treatment will be used depending on the type of cancer but drug therapy is the mainstay of treatment, with therapies such as radiotherapy and surgery being used to treat localised problems such as pain or fracture risk.

3.3 Policy, legislation, regulation and commissioning

Policy

This guideline will address at least one of the aims in [Achieving world-class cancer outcomes - a strategy for England 2015-2020](#) (NHS England 2015) by helping to deliver a 'modern high quality service'. It will also look at care after treatment to improve outcomes as set out in [Commissioning cancer services](#) (Department of Health 2011) and [2010 to 2015 government policy: cancer research and treatment](#) (Department of Health 2013).

Legislation, regulation and guidance

This guideline will contribute to the evidence base for the commissioning of services for people with early and locally advanced breast cancer as set out in [Implementing the cancer taskforce recommendations: commissioning person-centred care for people affected by cancer](#) (NHS England 2016).

4 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

Our website has information about how [NICE guidelines](#) are developed.